

510(K) SUMMARY

510(K) Number K091781

OCT 16 2009

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5.3 Date Prepared:
 June, 2009

5.4 Trade Name:
 Guided Medical Positioning System (gMPS™)

5.5 Classification Name:
 Programmable diagnostic computer

5.6 Product Code:

DQK

5.7 Device Class:

II

5.8 Regulation Number:

870.1425

5.9 Panel:

Cardiovascular

5.10 Predicate Devices:

- The IC-PRO System, model version 3.2 [Paieon, Inc.] cleared under K083745.
- CARTO XP EP Navigation System, Version 9 [Biosense Webster, Inc.] cleared under K070240; hereinafter: CARTO System.
- Niobe Magnetic Navigation System w/Navigant Navigation Workstation [Stereotaxis Inc.] cleared under K060967; hereinafter: Niobe System.

5.11 Intended Use / Indication for Use:

The Guided Medical Positioning System (gMPST™) is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a gMPST™ enabled (equipped with a gMPST™ sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.

5.12 Device Description:

The gMPST™, used in conjunction with an X-ray System, employs magnetic positioning technology to track a gMPST™ enabled diagnostic or therapeutic invasive device for the 3D position relative to any X-ray image, in real-time or previously recorded cine-loop.

The gMPST™ system is intended to provide the following:

Catheter tip positioning and navigation - The real time position of the gMPST™ sensor (and thus of the gMPST™ enabled device) is displayed in real time ("Live") fluoroscopy mode or in a recorded mode.

Smart trace (foreshortening indication) - A 3D trace of the gMPST™ enabled device trajectory is projected and superimposed on the 2D X-ray images (either on live fluoroscopy, recorded cine-loop or recorded still image).

3D reconstructed model - The system reconstructs a 3D model of the inspected anatomical structure.

Quantitative longitudinal measurements - The measurements are based on the 3D trace, thus overcoming length measurement errors induced by the foreshortening effect.

Quantitative Coronary Angiography (QCA) - While working in conjunction with gMPST™ enabled coronary device, the gMPST™ provides 3D QCA.

Virtual landmarking - A manually marked point or region of interest superimposed on X-ray images (real-time angiography and cine-loop) and on the 3D reconstruction.

5.13 Substantial Equivalence:

The intended use and indications for use of the gMPST™ are similar to or encompassed within the intended use and indications for use of its predicate devices. In addition, the gMPST™ has substantially similar technological characteristics, as well as principles of operation, as its predicate devices. Specifically, the gMPST™ and its predicates use magnetic technology for navigating invasive devices through tissue.

Performance testing was conducted in order to demonstrate the performance and accuracy of the gMPST™ and to verify that it does not raise any new safety and effectiveness issues in comparison to its predicate devices.

Tests results indicated that the gMPST™ is as safe and effective as its predicate devices for its intended use and is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness issues



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

OCT 16 2009

MediGuide, Ltd.
c/o Mr. Jonathan S. Kahan
Partner
Hogan & Hartson LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

Re: K091781
Trade/Device Name: gMPSTTM Guided Medical Positioning System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: October 8, 2009
Received: October 8, 2009

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

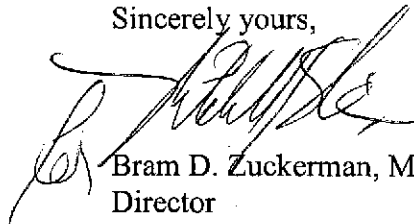
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K091781

Device Name: Guided Medical Positioning System (gMPSTTM)

Indications for Use:

The Guided Medical Positioning System (gMPSTTM) is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a gMPSTTM enabled (equipped with a gMPSTTM sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.

Prescription Use <u>✓</u> (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

10/16/09
Division of Cardiovascular Devices

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